UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: EPA Registration No.: 8340-UT; Shield™ Herbicide

From: Van M. Seabaugh VMS 3-8-93
Precautionary Review Section (PRS)
Registration Support Br.
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Jr., Head E 3/9/93
Precautionary Review Section
Registration Support Br.
Registration Division (H7505C)

To: JoAnn Miller (PM23)
Fungicide & Herbicides Br. (FHB)
Registration Division (H7505C)

Registrant:
Hoechst Celanese Corp.
P.O. Box 2500
Somerville, N.J.

Formulation From Label

Active Ingredients	
Glufosinate-ammonia: Ammonium-DL-homoalanine-4-yl-(methyl) phosphinate	1.0%*
Inert Ingredients	99.0%
	100.0%

*Equivalent to 0.08 pound of active ingredient per gallon.

Background Information

Five acute toxicity studies were submitted by FHB to the PRS for review. The studies were initially reviewed by our contractor (Clement International Corporation), and the secondary reviews were conducted by the PRS. The study reviews are provided (attachments). It is stated (MRID 423183-13) that Shield Herbicide (HOE 039866 OO SE01 A301) is a ready to use formulation containing 10g/L of glufosinate ammonium.

Results/Recommendations

The following acute toxicity studies were reviewed, and the results are as follows:

Test	MRID	Toxicity Category	Classification: core
Oral (§81-1)	423283-14	IV; limit test; LD50>5 g/kg.	Guideline
Dermal Toxicity (§81-2)	423183-15	III; limit test; LD50 >4g/kg.	Guideline
Inhalation (§81-3)	--	--	--
Eye Irritation (§81-4)	423183-16	--	Supplementary[1]
Eye Irritation (§81-4)	423183-17	III	Guideline[2]
Dermal Irritation (§81-5)	423183-18	IV	Guideline
Dermal Sensitization (§81-6)	--	--	--

[1] Stated (MRID 423183-16) was the following information, "...All prior testing on related, more concentrated formulations (Ignite 1 S C Herbicide, Arise Herbicide) had not resulted in such severe substained (sic) irritation with the thick yellow discharge. It is possible that this rabbit substained (sic) additional mechanical injury to the eye from handling or scratching the eye area. Due to the severe reaction, this animal was sacrificed after seven days and was excluded from the evaluation of ocular irritation..." [Note: From EPA's experience, we know that the occurrence of such an incidence of "additional mechanical injury" from handling or scratching is very rare. Also, we are not able to repute or substantiate the claims about "all prior testing on related, more concentrate formulations," because the registrant did not present the information at this time to enable us to make our own independent decision. This study is classified as "supplementary", because of the arbitrary decision to exclude one animal from the study].[2] An additional eye irritation study (tested 6 more rabbits; different laboratory) was submitted (MRID 423183-17) to help clarify the information reported in the first study (MRID 423183-16).

Labeling Recommendations

Based on the evaluation of the reviewed acute toxicity data and submitted label, we recommend deletion of the phrase "if irritation persists" from the following SOPT: "If On Skin: Wash

with plenty of soap and water. Get medical attention if irritation persists." "If irritation persists" is part of the Agency SOPT used for Toxicity Category III (dermal irritation test; §81-5), and not for the SOPT assigned for the dermal toxicity test (§81-2) results evaluated for this product (Toxicity Category III). Precautionary labeling must include the statement "Causes eye injury." The "If swallowed" statement is not required, but may be retained if the registrant desires. Data gaps exist for acute inhalation and dermal sensitization tests, and we cannot comment on any further labeling at this time. The environmental hazard statement should be changed to read as follows: "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark."

4.

DER 133-36

EPA Reg. No.: 8340-UT

DATA EVALUATION REPORT

GLUFOSINATE-AMMONIUM: SPRAY MIXTURE

Study Type: Acute Oral Toxicity

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer: Regina Cioffi — Date: 9/17/92

QA/QC Manager: Nancy McCarroll — Date: 9/17/92

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 133-154
Project Officer: James Scott

Approved by:

EPA Reviewer:

Signature: Dan M. Seabaugh
Date: 3-2-93

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-1; Acute oral toxicity in rats

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423183-14

PC Number:

TEST MATERIAL: Glufosinate-Ammonium: Spray Mixture

SYNONYM(S): HOE 039866, Ignite®

SPONSOR: Hoechst Celanese Corporation, Somerville, NJ

STUDY NUMBER: 91.0041

TESTING FACILITY: Pharma Research Toxicology and Pathology, Hoechst Aktiengesellschaft, Frankfurt, Germany

TITLE OF REPORT: Glufosinate-Ammonium: Spray Mixture: 10 g/l (Code: HOE 039866 00 SE01 A301); Testing for Acute Oral Toxicity in the Male and Female Wistar Rat

AUTHOR(S): Ehling, G. and Leist, K.- H.

STUDY COMPLETED: March 20, 1991

CONCLUSIONS: Acute oral LD_{50} in males: > 5000 mg/kg
Acute oral LD_{50} in females: > 5000 mg/kg
Acute oral LD_{50} in sexes combined: > 5000 mg/kg

CORE CLASSIFICATION: Core-Guideline. This study satisfies the Guideline requirements (81-1) for an acute oral toxicity study.

TOXICITY CATEGORY: IV ~~(Caution)~~

A. MATERIALS

Test Compound

Test material:	Glufosinate-Ammonium; Spray Mixture
Concentration:	~~1.0% Test material (%w/w)~~ 6mC neat
Identification number:	C00021/010
Active ingredient:	Not provided
Formulation:	10 g/L Glufosinate-Ammonium
Purity:	Not provided
Physical description:	Light blue fluid
Storage condition:	Darkness at ~20°C in an exhaustion cabinet
Stability:	24 months at 25°C

Dose level: 5000 mg/kg; administered as a 50% solution in deionized water.
Dosing volume: 10 ml/kg

Controls: None

Test Animals

Species: Rat
Strain: Hoe: WISKf(SPF71)
Source: HOECHST AG, Kastengrund, SPF breeding colony
Sex: 5 males; 5 females
Age: 6 weeks
Mean Body Weight: Males, 186 g; Females, 159 g (at dosing)
No. animals/dose: 10

Environmental conditions: Temperature: 22 ± 3°C
Humidity: 30 - 70%
No. air changes per hour: Not provided
Photoperiod: 12 hours

B. TEST PERFORMANCE

Animals Fasted: 16 hours prior to dosing

Dosing: The test material was prepared in deionzied water to yield a 50% solution, and distributed homogeneously with a magnetic stirrer. The test solution was administered once by oral gavage.

Observation Period: 15 days

Observation Frequency: Six times on the day of dosing, twice daily until day 6, and once daily thereafter.

Body Weight Interval: Days 0, 8 and 15

Gross Pathology: YES X ; NO _____

Histopathology: YES _____; NO X

C. RESULTS

Mortality: No unscheduled deaths occurred during the study.

Clinical Observations: Clinical signs of toxicity were similar for males and females. The animals exhibited drawn in flanks, a squatting posture and stilted gait for six hours following administration. All animals appeared normal for the remainder of the observation period.

Body Weights: All animals gained weight over the 15 day observation period.

Gross Necropsy: No gross abnormalities were observed.

LD_{50} Determination: Glufosinate-ammonium: (spray mixture) was tested up to the limit dose of 5000 mg/kg. No deaths occurred during this study; therefore, the LD_{50} is estimated to be greater than 5000 mg/kg in both male and female rats. This value corresponds to Toxicity Category: IV (Caution).

D. REVIEWER'S COMMENTS: We are in agreement with the authors that the acute oral LD_{50} for glufosinate-ammonium; spray mixture in rats is greater than 5000 mg/kg under study conditions. This product is a light blue fluid, and should have been tested undiluted. Dilution (Concentration) can be a factor in toxicity. OMS

E. QUALITY ASSURANCE MEASURES

Was the test performed under GLPs? YES X ; NO ____
A Quality Assurance Statement, signed and dated April 8, 1992 was submitted.

DER 133-37

DATA EVALUATION REPORT

GLUFOSINATE-AMMONIUM: Spray Mixture

EPA Reg. No.: 8340-UT

Study Type: Acute Dermal Toxicity

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer: Regina Cioffi — Date: 9/16/92

Regina Cioffi

QA/QC Manager: Nancy L. McCarroll — Date: 9/17/92

Nancy McCarroll

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 133-155
Project Officer: James Scott

Approved by:

EPA Reviewer:

Signature: Dan M. Seabaugh
Date: 3-2-93

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-2; Acute dermal toxicity

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423183-15

PC Number:

TEST MATERIAL: Glufosinate-Ammonium: Spray Mixture

SYNONYM(S): HOE 039866, Ignite®

SPONSOR: Hoechst Celanese Corporation, Somerville, NJ

STUDY NUMBER: 91.0044

TESTING FACILITY: Pharma Research Toxicology and Pathology, Hoechst Aktiengesellschaft, Frankfurt, Germany.

TITLE OF REPORT: Glufosinate-Ammonium: Spray Mixture: 10 g/l (Code: HOE 039866 00 SE01 A301); Testing for Acute Dermal Toxicity in the Male and Female Wistar Rat

AUTHOR(S): Ehling, G and Leist K.- H.

STUDY COMPLETED: March 27, 1992

CONCLUSIONS: Acute dermal LD_{50} in males: > 4000 mg/kg
Acute dermal LD_{50} in females: > 4000 mg/kg
Acute dermal LD_{50} in sexes combined: > 4000 mg/kg

CORE CLASSIFICATION: Core Guideline. This study satisfies the Guideline requirements (81-2) for an acute dermal toxicity study. Although a minor deviation from Guideline procedures regarding skin preparation was noted, it did not affect the outcome of the study. The time interval between skin preparation and application was not reported.

TOXICITY CATEGORY: III ~~(Caution)~~

A. MATERIALS

Test Compound

Test material:	Glufosinate-Ammonium: Spray Mixture
~~Concentration:~~	~~1% test material (%w/w)~~ DMS
Identification number:	C00021/010
Active ingredient:	Not provided
Formulation:	10 g/L Glufosinate-Ammonium
Purity:	Not provided
Physical description:	Blue liquid
Storage condition:	Darkness at ~ 20°C in an exhaustion cabinet
Stability:	24 months at 25°C

Dose level: 4000 mg/kg (undiluted)

Test Animals

Species: Rat
Strain: Hoe: WISKf(SPF71)
Source: HOECHST AG, Kastengrund, SPF breeding colony
Sex: 5 male, 5 female
Age: Males: 9 weeks; Females 12 weeks
Mean Body Weight: Males: 268 g; Females; 217 g (at dosing)
No. animals/dose: 10

Environmental conditions: Temperature: 22 ± 3°C
Humidity: 30 - 70%
No. air changes per hour: Not provided
Photoperiod: 12 hours

B. TEST PERFORMANCE

Application: At an unspecified time before dermal treatment, hair was shaved from the dorsal skin of the animal over an area ~ 30 cm^2. The undiluted test material was applied to the shaved area and covered with aluminum foil (48cm^2) and held in place with an elastic bandage to prevent the animals from ingesting the test material. After a dermal exposure period of 24 hours, the bandage was removed and the treated area was washed with warm water.

Observation Period: 15 days

Observation Frequency: Animals were observed 5 times on the day of dosing, twice daily until day 6, and then once daily until the end of the 15 day observation period.

Body Weight Interval: Days 1, 8 and 15

Gross Pathology: YES __X__; NO _____

Histopathology: YES _____; NO __X__

C. RESULTS

Mortality: No unscheduled deaths occurred during the study.

Clinical Observations: Two animals exhibited erythema on Day 2, which cleared by Day 4. Dry rough skin (4/5 animals), and fine (3/5 animals) and coarse (2/5 animals) scales were observed on Day 3. Dermal reaction cleared in all but one animal by the end of the observation period.

Body Weights: All animals gained weight over the observation period.

Gross Necropsy: No gross abnormalities were observed.

LD_{50} Determination: Since no deaths were noted during this study, the acute dermal LD_{50} for Glufosinate-Ammonium is greater than 4000 mg/kg in both male and female rats. This value corresponds to Toxicity Category: III (Caution).

D. REVIEWER'S COMMENTS: We agree with the study authors that the acute dermal LD_{50} for Glufosinate-Ammonium: Spray Mixture 10 g/l in rats is greater than 4000 mg/kg under study conditions. There were no deaths at 4000 mg/kg, therefore, this is a limit test.

The study is considered Core Guideline, although, the time interval between skin preparation and application was not reported, the outcome of the study was not affected.

E. QUALITY ASSURANCE MEASURES

Was the test performed under GLPs? YES _X_; NO ____
A Quality Assurance Statement, signed and dated April 29, 1992 was submitted.

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DER133-38

EPA Reg No.: 8340-47

DATA EVALUATION REPORT

Glufosinate-Ammonium: Spray Mixture

Study Type: Primary Eye Irritation in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Regina Cioffi Date 9/17/92
Regina Cioffi

QA/QC Manager Nancy L. McCarroll Date 9/17/92
Nancy McCarroll

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 133-156
Project Officer: James Scott

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Approved by:

EPA Reviewer:

Signature: Dan M. Seabaugh
Date: 3-2-93

EPA Reg. No.: 8340-UT

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-4: Primary eye irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423183-16

PC Number:

TEST MATERIAL: Glufosinate-Ammonium: Spray Mixture

SYNONYM(S): HOE 039866, Ignite®

SPONSOR: Hoechst Celanese Corporation, Somerville, NJ

STUDY NUMBER: 91.0043

TESTING FACILITY: Pharma Research Toxicology and Pathology, Hoechst Aktiengesellschaft, Frankfurt, Germany

TITLE OF REPORT: Glufosinate-Ammonium: Spray Mixture: 10 g/l (Code: HOE 039866 00 SE01 A301); Testing for Primary Eye Irritation in the Rabbit

AUTHOR(S): Hack, R. and Leist K.- H.

STUDY COMPLETED: March 12, 1991

CONCLUSIONS: The test substance caused ocular effects in 5/6 test animals which included slight to moderate inflammation of the iris, conjunctival reddening, chemosis, and discharge. All irritation cleared within 3 days.

CORE CLASSIFICATION: Core ~~Minimum~~ Supplementary. This study does not satisfies the Guideline requirements (81-4) for a primary eye irritation study. ~~One deviation concerning test material application was noted~~. This study is classified as Supplementary, because of the arbitrary decision to exclude one animal from the study.

TOXICITY CATEGORY: ~~III (Caution)~~

GMS

A. MATERIALS

Test Compound

Test material:	Glufosinate-Ammonium: Spray Mixture
Concentration:	~~1% test material (%w/w)~~ bms
Identification number:	C00021/010
Active ingredient:	Not provided
Formulation:	10 g/L Glufosinate-Ammonium
Purity:	Not provided
Physical description:	Light blue fluid
Storage condition:	Darkness at ~20°C in an exhaustion cabinet
Stability:	24 months at 25°C

Dose level: 0.1 mL (undiluted)

3. Test Animals

Species: Rabbit
Strain: New Zealand Albino
Source: HOECHST AG, Kastengrund
Number of animals: 6
Sex: Female
Age: 3 - 5 months
Body weight: 2000-3100 g (at dosing)
Environmental conditions: Temperature: 20 ± 3°C
Humidity: 30 - 70%
No. air changes per hour: Not provided
Photoperiod: 12 hours

B. TEST PERFORMANCE

1. Eye Examination: Approximately 24 hours prior to testing, all eyes were examined for corneal lesions under UV light after the instillation of fluorescein-sodium 1% solution. None of the animals selected for the study exhibited ocular abnormalities.

2. Test Material Application: The test material was placed in the lower conjunctival sac of the left eye of each animal. The right eye of each animal served as the untreated control. The treated eye was washed out with physiological saline 24 hours after application of the test material, and at all of the designated exam times if discharge was present, or when a corneal examination with fluorescein-sodium solution took place.

3. Observation Period: The eyes were examined and scored for ocular lesions at 1, 24, 48 and 72 hours. Some effects were still present after 72 hours, therefore, the observation period was extended to 7 days.

4. Scoring System: Eyes were examined and scored for ocular lesions using the ~~EPA~~ Irritancy Index below:
bms

~~EPA Irritancy Index~~ cms

Irritancy Index	Classification
0 - 10	non-irritating
11 - 20	slightly irritating
26 - 56	moderately irritating
57 - 110	severely irritating

C. REPORTED RESULTS: A summary of ocular effects is presented below:

Summary of Incidence of Positive Ocular Effects

	Observation Intervals						
	Hour				Day		
	1	24	48	72	7	14	21
Cornea							
Opacity	0/6	1/6	1/6	0/6	1/6	0/5[a]	--
Iris							
Iritis	2/6	1/6	1/6	1/6	0/6	0/5	--
Conjunctivae							
Redness	6/6	2/6	1/6	1/6	1/6	0/5	--
Chemosis	2/6	2/6	1/6	1/6	1/6	0/5	--
Discharge	6/6	2/6	1/6	1/6	1/6	0/5	--

[a] one animal was sacrificed at day 7

One animal had very severe ocular lesions from 24-48 hours, which cleared by 72 hours, and then reappeared and persisted until Day 7. The animal was sacrificed on Day 7. The lesions noted in this animal were not considered treatment related, and not considered in the assessment of reversibility. The test material caused slight to moderate inflammation of the iris in 2/6 animals on Day 1 and in 1/6 animals until Day 3. Minor conjunctival reddening, chemosis, and clear and colorless discharge were caused by the test material and persisted until Day 7. According to the EPA Irritancy Index for ocular lesions, a maximum irritancy index of 12.7 was calculated after one hour.

cms ~~Based on these findings, Glufosinate Ammonium: Spray Mixture is classified as Toxicity Category: III (Caution).~~

D. ~~REVIEWERS' COMMENTS: We are in agreement with the study authors that Glufosinate-Ammonium: Spray Mixture: 10 g/l causes ocular effects that~~ cms ~~cleared within 3 days in all animals (except the animal with non-substance~~

DMS ~~related lesions). It was further noted that the data were in good agreement with the results of an independently performed eye irritation study conducted by a different laboratory with the same formulation of test material.~~

DMS ~~This study is considered Core Minimum for the following reason:~~

- Eyelids were not reported to be held closed for one second after application of the test material to prevent possible immediate loss of the test material.

E. QUALITY ASSURANCE MEASURES: The test was performed under GLPs (A quality assurance statement was signed and dated December 12, 1991).

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DER133-39

DATA EVALUATION REPORT

IGNITE®

Study Type: Primary Eye Irritation in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Regina Cioffi Date 9/17/92
Regina Cioffi

QA/QC Manager Nancy E. McCarroll Date 9/17/92
Nancy McCarroll

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 133-157
Project Officer: James Scott

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Approved by:

EPA Reviewer:

Signature: Dan M. Seabaugh
Date: 3-1-93

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-4: Primary eye irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423183-17

PC Number:

TEST MATERIAL: Ignite®; Glufosinate-Ammonium

SYNONYM(S): HOE 039866 00 SE 01 A3

SPONSOR: Hoechst-Roussel Agri-Vet Company

STUDY NUMBER: 327-163

TESTING FACILITY: International Research and Development Corporation, Mattawan, Michigan

TITLE OF REPORT: Eye Irritation Study of Ignite® (HOE 039866 00 SE 01 A3) in Rabbits

AUTHOR(S): Myer, J.

STUDY COMPLETED: March 27, 1992

CONCLUSIONS: The test material produced moderate conjunctival redness, slight to moderate discharge and slight swelling, all of which cleared within 72 hours. There was no corneal or iridal involvement during the study.

CORE CLASSIFICATION: Core Guideline. This study satisfies the Guideline requirements (81-4) for a primary eye irritation study. ~~Although a minor deviation concerning the time of the initial eye examination was noted, it did not affect the outcome of the study~~. Unsatisfactory (not confirmed)

TOXICITY CATEGORY: ~~III (Caution)~~ IV Unsatisfactory

The scores were all zeros (1, 24, 48, & 72 hr. post-dosing) except for "positive" conjunctivael scores only seen at the 1-hr. observation.

A. MATERIALS

Test Compound

Test material:	Ignite®; Glufosinate-Ammonium
~~Concentration:~~	~~1% (w/w)~~
Identification number:	HOE 039866 00 SE 01 A3
Active ingredient:	Not provided
Formulation:	Not provided
Purity:	Not provided
Physical description:	Blue liquid
Storage condition:	Sealed container at room temperature
Stability:	Not provided

Dose level: 0.1 mL (undiluted)

3. Test Animals

Species: Rabbit
Strain: New Zealand White [HRA:(NZW)SPF]
Source: Hazleton Research Products, Inc., Kalamazoo, Michigan
Number of animals: 6
Sex: Male 3; Female 3
Age: 5.5 months
Mean body weight: 3234-3806 g (at dosing)
Environmental conditions: Temperature: Not provided
Humidity: Not provided
No. air changes per hour: Not provided
Photoperiod: 12 hours

B. TEST PERFORMANCE

1. Eye Examination: Eyes were examined during the 63 day quarantine period with sodium fluorescein. None of the animals selected for the study exhibited physical defects or corneal lesions.

2. Test Material Application: The test substance was placed in the lower conjunctival sac of the right eye of each animal. The eyelids were gently held together for one second. The left eye of each animal served as the untreated control. The treated eyes ~~were not washed after the exposure period~~ remained unwashed.

3. Observation Period: Both eyes of each animal were evaluated for evidence of ocular irritation at 1, 24, 48 and 72 hours after dosing. Sodium fluorescein examinations were conducted at 72 hours.

4. Scoring System: Eyes were examined and scored for ocular lesions using the Draize scoring system.

C. REPORTED RESULTS: A summary of ocular effects is presented below:

Summary of Incidence of Positive[a] Ocular Effects

	Observation Intervals								
	Hour				Day				
	1	24	48	72	4	7	19	14	21
Cornea Opacity	0/6	0/6	0/6	0/6	--	--	--	--	--
Iris Iritis	0/6	0/6	0/6	0/6	--	--	--	--	--
Conjunctivae									
Redness	4/6[b]	1/6	0/6	0/6	--	--	--	--	--
Chemosis	0/6	0/6	0/6	0/6	--	--	--	--	--
Discharge	4/6	0/6	0/6	0/6	--	--	--	--	--

[a]The following grades for each tissue are considered positive:

Opacity (Density) - Grades 1, 2, 3, and 4
Iris - Grades 1 and 2
Conjunctivae (Redness) - Grades 2 and 3
(Chemosis) - grades 2, 3, and 4

[b]Two animals had scores < 2

Slight (2 animals) to moderate (4 animals) conjunctival redness was observed in all animals at 1 hour. Three animals exhibited (grade 1) chemosis at 48 hours, which cleared within 72 hours. Slight to moderate discharge was observed in four animals at one hour but cleared by 24 hours. Slight swelling (grade 1) was observed in three animals at one hour, and cleared by 24 hours. There was no corneal or iridal irritation.

Based on these findings IGNITE® is classified as Toxicity Category: ~~III (Caution)~~ IV Oms.

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D. REVIEWERS' COMMENTS: We agree with the study author that IGNITE® did not cause corneal or iridal irritation under study conditions. IGNITE® caused conjunctival irritation that cleared in all animals within 48 hours.

This study is considered Core Guideline, ~~although the initial eye examination did not take place within 24 hours of the test application, the outcome of the report was unaffected~~. 0ms The eyes were examined at 1, 24, 48, and 72 hours after dosing.

E. QUALITY ASSURANCE MEASURES: The test performed under GLPs (A quality assurance statement was signed and dated March 27, 1992).

2.2

DER 133-40
EPA Reg. No.: 8340-UT

DATA EVALUATION REPORT

GLUFOSINATE-AMMONIUM

Study Type: Primary Dermal Irritation in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Regina Cioffi Date 9/17/92
Regina Cioffi

QA/QC Manager Nancy E. McCarroll Date 9/17/92
Nancy McCarroll

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 133-158
Project Officer: James Scott

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Approved by:

EPA Reviewer:

Signature: Dan M. Seabaugh
Date: 3-2-93

EPA Reg. No.: 8346-UT

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-5: Primary dermal irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423183-18

PC Number:

TEST MATERIAL: Glufosinate-Ammonium: Spray Mixture

SYNONYM(S): HOE 039866

SPONSOR: Hoechst Celanese Corporation, Somerville, NJ

STUDY NUMBER: 91.0042

TESTING FACILITY: Pharma Research Toxicology and Pathology, Hoechst Aktiengesellschaft, Frankfurt, Germany.

TITLE OF REPORT: Glufosinate-Ammonium: Spray Mixture: 10 g/l (Code: HOE 039866 00 SE01 A301) Testing for Primary Dermal Irritation in the Rabbit

AUTHOR(S): Hack, R. and Leist, K.- H.

STUDY COMPLETED: March 8, 1991

Primary Irritation Score = 0.17 bms

CONCLUSIONS: Skin Irritation Score: 0.17; non-irritating

CORE CLASSIFICATION: Core Guideline. This study satisfies the Guideline requirements (81-5) for a primary dermal irritation study.

TOXICITY CATEGORY: IV ~~(Caution)~~ bms

A. MATERIALS

Test Compound

Test material:	Glufosinate-ammonium; spray mixture
Concentration:	~~1% test material (%w/w)~~ 0.5 mL
Identification number:	C00021/010
Active ingredient:	Not provided
Formulation:	Not provided
Purity:	Not provided
Physical description:	Light blue fluid
Storage condition:	Darkness at - 20°C in an exhaustion cabinet
Stability:	24 months at 25°C

Dose levels: 0.5 mL / patch (undiluted)

3. Test Animals

Species: Rabbit
Strain: New Zealand Albino
Source: HOECHST AG, Kastengrund
Number of animals: 6
Sex: Female
Age: 3-5 months
Body weight: 2600-3700 g (at dosing)
Environmental conditions: Temperature: 20 ± 3°C
Humidity: 30 - 70%
No. air changes per hour: Not provided
Photoperiod: 12 hours

B. TEST PERFORMANCE

1. Skin Preparation: About 24 hours prior to testing, the dorsal area of the trunk of each animal was clipped, and 1 test site (measuring ≈ 25 cm^2) was selected.

2. Test Material Application: A piece of surgical plaster with a 2.5 cm^2 cellulose patch was placed over the test site and the test substance was applied underneath. The area was then covered with a semi-occlusive bandage. After 4 hours of exposure, the patch was removed; residual test material was removed with warm tap water.

3. Observation Period: The test sites were observed for erythema, edema and other dermal irritation at 30-60 minutes and at 24, 48 and 72 hours.

4. Scoring System: The treated area was examined for edema, erythema and eschar formation according to the Draize Scoring Method.

Irritancy Index	Classification
0.0 - 0.5	non-irritating
0.6 - 3.0	slightly irritating
3.1 - 5.0	moderately irritating
5.1 - 8.0	severely irritating

C. REPORTED RESULTS: One test animal exhibited slight erythema, edema and rough dry skin, all of which cleared within 72 hours. No systemic signs of toxicity were observed. Based on these results, the Primary Irritation Score is 0.17 and Glufosinate-Ammonium:Spray Mixture is, therefore, classified as Toxicity Category: IV ~~(Caution)~~.

D. REVIEWERS' COMMENTS: We are in agreement with the author that Glufosinate-ammonium spray mixture is non-irritating and caused only a slight dermal reaction in rabbits under the study conditions.

E. QUALITY ASSURANCE MEASURES: The test performed under GLPs (A quality assurance statement was signed and dated December 16, 1992).

Tox Chem. No. 467AB (glufosinate) File Last Updated Current Date

Study/Species/Lab/Study# Date	Material EPA Reg. No.: 8340-UT	MRID No.	Results	Tox. Cat.	Core Grade
Acute toxicity Oral toxicity (81-1); Rat Pharma Research Toxicology & Pathology 91.0041 2/20/91	Glufosinate-Ammonium (spray mixture 10 g/l)	423183-14	LD50 > 5000 mg/kg Limit Test	IV	Guideline
Dermal toxicity (§81-2); Rat Pharma Research Toxicology & Pathology 91.0044 3/27/92	Glufosinate-Ammonium (spray mixture 10 g/l)	423183-15	LD50 > 4000 mg/kg Limit Test	III	Guideline
Eye irritation (§81-4); Rabbit Pharma Research Toxicology & Pathology 91.0043 3/12/92	Glufosinate-Ammonium (spray mixture 10 g/l)	423183-16	Slight-moderate inflammation of iris, conjunctival irrit. One rabbit arbitrarily excluded from study (opacity, iritis, conjunctivitis)	~~III~~	Supplementary bms ~~Minimum~~
Eye irritation (§81-4); Rabbit International Research & Devlelopment 327-163 3/27/92	Ignite Glufosinate-Ammonium (spray mixture 10 g/l)	423183-17	Mod. conjunctival redness, discharge and swelling	III	Guideline
Dermal irritation (§81-5); Rabbit Pharma Research Toxicology & Pathology 91.0042 3/8/92	Glufosinate-Ammonium (spray mixture 10 g/l)	423183-18	Non-irritating P.I.I = 0.17	IV	Guideline